

REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Applicants thank the Examiner for withdrawing the finality of the last Office Action.

Claims 1-11, 23, 24, 28 and 46-52 were pending in this application. Claims 46-52 have been clarified to recite a parasitological formulation for proper claim dependency. Claim 50 is amended to spell out the abbreviations, which are well known to one of skill in the art. Support is also found in ¶¶ 342 and 346 of the specification as published. Claims 53-55 are added. Support for claims 53-55 may be found throughout the specification as originally filed and in particular, Examples 1-4.

No new matter has been added.

The Examiner is thanked for indicating that claims 1, 23, and 28 drawn to the elected crystallization inhibitor, transcutol and ethanol with actives consisting of only fipronil and amitraz would be non obvious over the art of record, which Applicants have made every effort to address with claims 53-55.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTIONS ARE OVERCOME

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Office Action, abbreviations should be spelled out at first appearance in claims. In response, claim 50 has been amended to spell out the abbreviations, which are well known to one of skill in the art.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, second paragraph, are respectfully requested.

II. THE 35 U.S.C. §103 REJECTIONS ARE OVERCOME

Claims 1-11, 23, 24, 28, and 46-57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over LAMM WO 03/015519 in view of HUET et al 64842425 and TENG- '93.

The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727. Furthermore, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, the references relied upon by the Office Action does not disclose, suggest or enable Applicants' invention. Applicants respectfully disagree with the characterization that there is no distinction between pour on and spot on in the claimed instant compositions. The recitations of pour on and spot on are in the preamble, which is a limitation of the instant claims; and, the surprising superiority of the instant invention is demonstrated in the present application.

Applicants respectfully disagree with the characterization that there is no distinction between pour on and spot on in the claimed instant compositions. The recitations of pour on and spot on are in the preamble, which is a limitation of the instant claims.

In this regard, the Examiner is respectfully reminded that ALL words in the claims must be considered in evaluating the patentability of the claims over the prior art. *In re Wilson*, 165;

see also *In re Swinehart*, 169 U.S.P.Q. 227 (C.C.P.A. 1971) ("point of novelty" was "transparen[cy]"; Court held that "functional" or "use" language was permissible, even at the "point of novelty" indicating that "there is nothing intrinsically wrong" with claiming by what something does); *In re Duva*, 156 U.S.P.Q. 90 (C.C.P.A. 1967) (prior art rejection of aqueous solution "for depositing gold" reversed due to PTO failure to consider the "for depositing gold" recitation because "all factual differences which may be properly noted in any portion of a claim must be included within the basis for comparison with the prior art if we are to properly evaluate the difference between the invention defined in a claim and the teachings of a reference", i.e., "every portion of the ... claims must be considered"). For instance, it is well-established law that where the preamble is essential to point out the claimed invention and give meaning and vitality to the claim, it is given the effect of a limitation. See, e.g., *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671, F.2d 1359, 213 U.S.P.Q. 89 (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Walles et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); *Smith v. Bousquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940); *Ex parte Varga*, 189 U.S.P.Q. 204 (P.O.B.A. 1973); see also *Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951).

The Examiner is directed to the Examples of the specification which illustrate the unexpected effects of the present invention. The formulation according to the present invention remained effective for a far longer period of time than a formulation comprising fipronil alone. This enhanced efficacy is surprising since amitraz is not known in the art to be used in treating flea or tick infestations on mammals and birds. In fact, the Office Action admits that TENG relates to the use of amitraz in treating mites (not fleas or ticks).

Therefore, Applicants respectfully submit that nonobvious and unexpected results are derived from the invention as presently claimed.

According to Example 5, the fipronil/amitraz combination of the present invention remained effective for a far longer period of time than fipronil alone. For example, the fipronil/amitraz combination is over twice as effective at 58 days after treatment against ticks on dogs than fipronil alone.

According to Example 6, the fipronil/amitraz combination of the present invention exhibits a faster rate of efficacy than a formulation comprising fipronil alone. For example,

speed of efficacy of the fipronil/amitraz combination is 4 to 5 times as fast against ticks on dogs than fipronil alone 21 to 42 days after treatment.

According to Example 7, the fipronil/amitraz combination of the present invention remained effective for a far longer period of time than fipronil alone. For example, the fipronil/amitraz combination is over twice as effective at 51 days after treatment against fleas on dogs than fipronil alone.

Therefore, contrary to the Office Action, Applicants have provided objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 103 are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein, and prompt issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,
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